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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/103,846	06/24/98	WOYCHIK	R CASE-03330

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EXAMINER

MARTIN, J

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/08/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

FILE

**Office Action Summary**Application No.  
**09/103,846**Applicant(s)  
**Woychik et al.**Examiner  
**Jill D. Martin**Group Art Unit  
**1632**☒ Responsive to communication(s) filed on Apr 24, 2000☒ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**☒ Claim(s) 1-34 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 30 and 33 is/are allowed.☒ Claim(s) 1-29, 31, 32, and 34 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicants' Amendment filed April 24, 2000 (Paper No. 6) has been entered. Claims 1, 3, 9, 13, 14, 15, 17, 23, 27, and 28 have been amended, and claims 29-34 have been added. Claims 1-34 are pending and are under current examination.

Prior rejections of record which are not made of record in the instant Office action have been withdrawn in view of Applicants' amendments to the claims.

#### *Information Disclosure Statement*

Applicants' Supplemental Information Disclosure Statement filed April 24, 2000 (Paper No. 8) has been considered.

#### *Inventorship*

The petition to correct the inventorship filed April 24, 2000 of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted.

A 37 CFR 3.73(b) submission has not been received to support action by the assignee.

#### *Claim Objections*

Applicants' amendments and/or amendments to the claims necessitated the new ground(s) of rejection as follows:

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Claims 3, 9, 17, 23, 31, and 34 are objected to because of the following informalities: In the prior Office action mailed 1/18/00 (Paper No. 5), a restriction requirement and election was set forth with regard to an election of the claims drawn to target cells of non-human animals. See page 2, and page 4 of the Office action, particularly page 4, wherein the Examiner indicated that the terms “cell” and “organism” are being examined only as they pertain to cells and organism from non-human animals.

However, claims 3, 17, 31, and 34 specifically recite the term “organism” and should be amended to “non-human animal” according to the restriction/election. In claims 9 (which depends from claim 1) and 23 (which depends from claim 15), the embryonic cells are limited to “non-human” embryonic cells, however, such cells are considered “non-human cells” in claims 1 and 15 according to the restriction/election. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' amendment and/or additions to the claims necessitated the new ground(s) of rejection as follows:

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Claims 1-12, 14-26, 28, 29, 31, 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods which recite isolated embryonic cells which are mouse embryonic stem cells, does not reasonably provide enablement for embryonic stem cells from all other non-human species of animals, and embryonic cells which are protocorm-like body and callus cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Please note that this rejection is only made on the recitation of the limitation “embryonic stem cells” and “protocorm-like” and “callus” cells. In particular, the claims which now recite “embryonic stem cells” are made only on the basis of the prior rejection under 35 U.S.C. §112, first paragraph, for reasons advanced on pages 3-7 of the prior Office action mailed 1/18/00 (Paper No. 5). Specifically, this rejection is made with regard to only those claims which recite “embryonic stem cells” which are not so limited to “mouse embryonic stem cells” and as the new claims are directed to “protocorm-like body” and “callus” cells. Note that the claim limitations of the same claims under rejection which are directed to “fertilized egg cells” and “2-cell embryos” are not included in this rejection.

Applicants argue that the specification also contemplates chimeric organisms which contain the transgene in only somatic cells in that such chimeric organisms can be used for determination of the function of the gene of interest, citing page 28, lines 15-21 of the specification. Here, the specification discusses, for example, various methods known in the art

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for detecting morphological and pathological changes relative to a wild-type animal. The specification further indicates that morphological changes as a result of modification in the gene of interest is useful for delineating formation of the structure whose morphology is altered by gene modification. See page 28. More particularly, the specification discusses that behavioral changes in an organism are measured as a result of gene modification. See page 29. As such, and in response to Applicants' arguments that chimeric animals are useful, it is maintained that embryonic stem cells other than mouse embryonic stem cells, as well as protocorm-like and callus cells, are not enabled by the specification because it is unclear how such cells contribute to the chimera. Even if such cells make some contribution, it appears from the specification (as a claim is read as its broadest reasonable interpretation that is consistent with the specification) that the cells must contribute to the formation of tissues of the whole animal or to the whole animal itself in order to convey the usefulness of the chimeric as well as of the embryonic cells themselves. Accordingly, only those cells well characterized in the art, at the time of the claimed invention, to give rise to the formation of tissues are enabled, e.g., mouse embryonic stem cells. Nowhere in the specification would one of skill in the art find guidance and/or direction for the use of embryonic stem cells of other non-human animal species or protocorm-like or callus cells for the contribution to tissues of a chimeric animal.

Please note that, with regard to claim breadth, the proper standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. In addition, when analyzing the enabled scope of the claims, the teachings of the

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specification are to be taken into account because the claims are to be given their broadest reasonable interpretation that is consistent with the specification. As such, it is maintained that the broadest reasonable interpretation of the claimed invention encompasses the use of embryonic stem cells and protocorm-like and callus cells for use for the contribution to the formation of tissues of a non-human animal, and such an embodiment (that is not specifically limited to mouse embryonic stem cells) is not enabled by the specification for the reasons of record and as discussed in the preceding paragraphs.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 4, 6, 7, 9-11, 13-16, 18, 20, 21, 23-25, 27, and 28 stand rejected under 35 U.S.C. 102(a) as being anticipated by Thomas et al.

The Katz Declaration under 37 CFR 1.132 filed April 24, 2000 is insufficient to overcome the rejection of the claims based upon the rejection as set forth in the last Office action because:

The inventive entity differs from the inventive entity of Thomas et al. after removal of Christian LaMantia. While the petition for correction of the inventorship has not been granted for

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the addition of James Thomas, it is noted that even after addition of this inventor, the inventive entity still would differ by one inventor, Richard Woychik.

### *Conclusion*

Claims 3, 5, 8, 12, 17, 19, 22, 24-26, and 29-34 appear to be free of the cited prior art of record because the cited prior art of record fails to teach *in vitro* mutagenesis of embryonic stem cells (other than mouse embryonic stem cells), fertilized egg cells, 2-cell embryos, protocorm-like, or callus cells for the modification of a gene of interest in the cells, and use of the cells for the generation of a chimeric non-human animal, as well as the use of chemical agents for single and double strand breaks in the gene of interest. However, certain of these claims are subject to another rejection. Claims 30 and 33 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill Martin whose telephone number is (703)305-2147.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at (703)305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Jill D. Martin

Patent Examiner

*Karen M. Hauda*  
KAREN HAUDA  
PRIMARY EXAMINER